



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicine overview — recent updates

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An agency of the European Union





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Medicine overview

Information about an authorised medicine is published as an
EPAR (European public assessment report).

Key points are summarised in lay language in the medicine overview.

Public-friendly
overview of the
medicine and why
it is authorised



Written by EMA,
reviewed by experts,
committee members
and patients

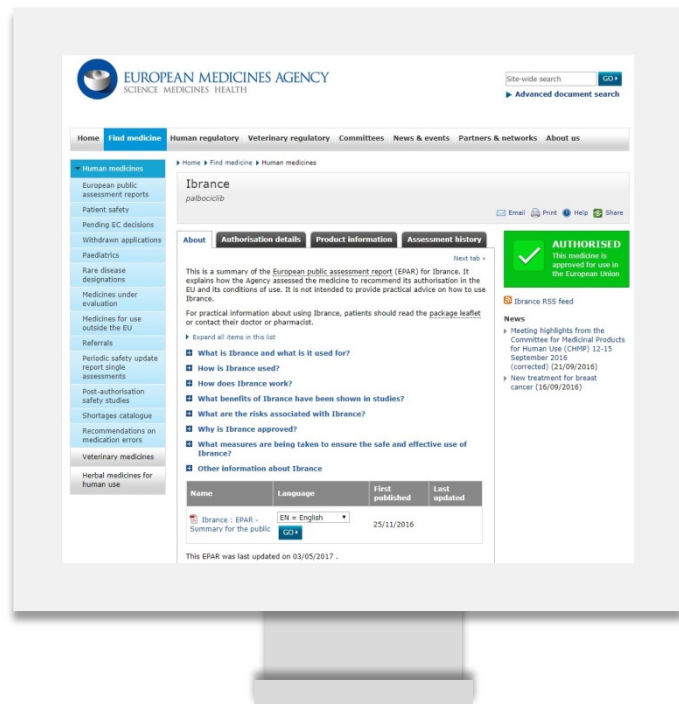


Translated into all
official EU languages





Where to find the overview



1. Go to EMA website (www.ema.europa.eu)
2. Type medicine name in 'Find medicine' search box

Value of patient/consumer review



• Unique **perspective**



• Patients and public **concerns**



• Appropriate use of **language**



Patient feedback

“The name EPAR summary does not mean anything to people outside EMA.”

“It is important to convey that the medicine is under constant monitoring (pharmacovigilance).”

“Long introductory text is not needed.”

“Where is the advice to read the PL or contact your doctor or pharmacist for more information?”

“Reduce references to committees and internal EMA and regulatory procedures.”

“People do not know EMA and will not come to the EMA website for medicines information, but will go to unauthorised sources”



Updates

1

• **Name change:** from 'EPAR summary for the public' to 'An overview of <medicine> and why it is authorised in the EU'

2

• **Remove introduction** text, enhance **Search engine Optimisation**

3

• **Remove mentions of committees/regulatory** processes

4

• Point to package leaflet, advise to consult HCP in section about use of medicine

5

• Text changes to increase **clarity and consistency**

6

• Add information on **side effects monitoring**



EPAR summary for the public

Tecentriq atezolizumab

This is a summary of the European public assessment report (EPAR) for Tecentriq. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice.

For practical information about using Tecentriq, ask your doctor or pharmacist.

What is Tecentriq and what is it used for?

Tecentriq is a cancer medicine for treating urothelial carcinoma (a cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer.

Tecentriq (*atezolizumab*)

An overview of Tecentriq and why it is authorised in the EU

What is Tecentriq and what is it used for?

Tecentriq is a cancer medicine for treating urothelial carcinoma (a cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer.

Tecentriq is used when these cancers are advanced or have spread to other parts of the body. For urothelial carcinoma, the medicine is for patients who have tried platinum chemotherapy before or are ineligible for treatment with cisplatin. Patients with non-small cell lung cancer should first have had



How is Tecentriq used?

Tecentriq is given as an infusion (drip) into a vein every 3 weeks and treatment should continue for as long as the patient benefits from it or does not suffer from unmanageable side effects. Treatment may need to be stopped in patients experiencing certain side effects including inflammation in lungs, liver or bowel,

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What measures are being taken to ensure the safe and effective use of Tecentriq?

The company that markets Tecentriq will put in place an educational program for patients and healthcare professionals to explain that serious immune-related side effects can occur during treatment and what they should do to minimize risks. The company is also carrying out and completing studies to provide more data on the effectiveness of Tecentriq in urothelial carcinoma and on the medicine's safety.

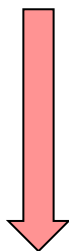
Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tecentriq have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tecentriq is continuously monitored. Side effects reported with Tecentriq are carefully evaluated and any necessary action taken to protect patients.



Other information about Tecentriq

The European Commission granted a marketing authorisation valid throughout the European Union for Tecentriq on 21 September 2017.



Other information about Tecentriq

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Thank you for valuable patient and consumer feedback

Further information

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